PLOUG8.001APC PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Agger et al.
Appl. No. : 10/563,731

Filed : January 6, 2006

For : ADJUVANT COMBINATIONS

OF LIPOSOMES AND MYCOBACTERIAL LIPIDS FOR

IMMUNIZATION

COMPOSITIONS AND VACCINES

Examiner : Unknown Group Art Unit : Unknown

REQUEST FOR CORRECTED PATENT PUBLICATION UNDER 37 C.F.R. 1.221(b)

Mail Stop PCT

Commissioner for Patents Mail Stop AF P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir-

Applicants hereby request correction of the title of Published US Patent Application No. 2006/0286128. There is a misspelled word ("MYCOBACTERIAIAL") in the title of the published application as shown on the enclosed, marked-up first page of the published application. This word should be -MYCOBACTERIAL--. Also enclosed herewith is the first page of the application as filed (PCT WO2005/004911) that shows the correct title. Thus, the proper title of the published application should be:

ADJUVANT COMBINATIONS OF LIPOSOMES AND MYCOBACTERIAL LIPIDS FOR IMMUNIZATION COMPOSITIONS AND VACCINES

Appl. No. : 10/563,731 Filed : January 6, 2006

> Because this is an error on the part of the USPTO, and the request is being made within two months of the publication date of December 21, 2006, no fees are believed due. However, if any fees are due, please charge Deposit Account No. 11-1410.

> > By:

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 21, 2007

Neil S. Bartfeld, Ph.D. Registration No. 39,901

Agent of Record Customer No. 20,995

(619) 235-8550

3452348 022107



(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2006/0286128 A1 Agger (43) Pub. Date: Dec. 21, 2006

424/248.1

(54) ADJUVANT COMBINATIONS OF MYCOBAC TERIAL Extraordinary LIPOSOMES AND APPCOBACTERIALS Coctadeey extract from LIPTOS FOR IMMUNIZATION adjuvant of COMPOSITIONS AND VACCINES

(76) Inventor: Else Agger, Copenhagen (DK)

Correspondence Address: KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 (US)

(21) Appl. No.: 10/563,731

(22) PCT Filed: Jul. 7, 2004

(86) PCT No.: PCT/DK04/00488

(30) Foreign Application Priority Data

Publication Classification

A61K 39/04 (2006.01) (52) U.S. CL

(51) Int. Cl.

(57) ABSTRACT

The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldioctade-cylammonium-bromide/duloride (DDA) and a lipid extract from The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldion.

eoctadecylammonium-bromide/chloride (DDA) and a lipid extract from <The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from Mycobacterium bovis. The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldcoctadecylammoniumbromide/chloride (DDA) and a lipid extract from Mycobacterium bovis<The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from Mycobacterium bovis BCG The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from Mycobacterium bovis BCG <The present invention provides a vaccin adjuvant consisting of a combination of a surfactant dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from Mycobacterium bovis BCG. The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from <i>Mycobacterium bovis BCG<i>. <The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammoniumbromide/chloride (DDA) and a lipid extract from <i>Mycobacterium bovis BCG<i>. The total lipid extract</ti> contains both apolar lipids, polar lipids, and lipids of intermediate polarity of which the apolar lipids were found to induce the most powerful immune responses. The total lipids may be extracted with chloroform/methanol and re-dissolved in water before the addition of surfactant. This preparation may be used to induce prominent cell-mediated immune responses in a mammal in order to combat pathogens, or as a treatment for cancer.

(19) World Intellectual Property Organization International Bureau



DK

(43) International Publication Date 20 January 2005 (20.01.2005)

PCT

(10) International Publication Number WO 2005/004911 A2

(51) International Patent Classification7: A61K 39/39.

39/04, A61P 31/06 (21) International Application Number:

PCT/DK2004/000488 (22) International Filing Date: 7 July 2004 (07.07.2004)

(25) Filing Language: English

(26) Publication Language:

English (30) Priority Data:

PA 2003 01046 9 July 2003 (09.07.2003) PA 2003 01403 27 September 2003 (27,09,2003)

(71) Applicant (for all designated States except US): STATENS SERUM INSTITUT [DK/DK]; Artillerivej 5, DK-2300 Copanhagen S (DK).

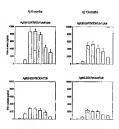
(72) Inventors; and (75) Inventors/Applicants (for US only): AGGER, Else, Marie [DK/DK]; Krudtmøllegårds Allé 9, DK-2300 Copenhagen S (DK). ANDERSEN, Peter [DK/DK]: Sparreholmvej 47, DK-2700 Brønshøj (DK). OLSEN, Anja [DK/DK]; Jacob Bulls Alle 121, DK-2860 Seborg (DK). ROSENKRANDS, Ida [DK/DK]; Kastaniehaven 9, DK-3500 Værløse (DK).

(74) Common Representative: TOFT, Lars; Statens Serum Institut, Corporate Affairs, Artillerivei 5, DK-2300 Copenhagen S (DK).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AR, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DB, DK, DM, DZ, EC, EE, EG, ES, FL GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD. MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH. PL. PT. RO. RU. SC. SD. SE. SG. SK. SL. SY TI. TM

[Continued on next page]

(54) Title: ADJUVANT COMBINATIONS OF LIPOSOMES AND MYCOBACTERIAL LIPIDS FOR IMMUNIZATION COM-POSITIONS AND VACCINES



WO 2005/004911 A2 ||||||

(57) Abstract: The present invention provides a vaccine adjuvant consisting of a combination of a surfactant i.e. dimethyldeoctadecylammonium-bromide/chloride (DDA) and a lipid extract from Mycobacterium bovis BCG. The total lipid extract contains both apolar lipids, polar lipids, and lipids of intermediate polarity of which the apolar lipids were found to induce the most powerful immune responses. The total lipids may be extracted with chloroform/methanol and re-dissolved in water before the addition of surfactant. This preparation may be used to induce prominent cell-mediated immune responses in a mammal in order to combat pathogens, or as a treatment for cancer.